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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/769,532	01/30/2004	Robert G. Whirley	760-251 RCEII	8638

23869 7590 08/20/2007
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EXAMINER	
SWEET, THOMAS	

ART UNIT	PAPER NUMBER
3738	

MAIL DATE	DELIVERY MODE
08/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/769,532	WHIRLEY ET AL.	
	Examiner	Art Unit	
	Thomas J. Sweet	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,18,19,21 and 36-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15,18,19,21 and 36-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Response to Arguments

Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments filed 07/02/2007 have been fully considered but they are not persuasive. Regarding claim 21, Kocur discloses use of adhesives, weld/fuse, etc. as attachments, which is one or more elements for connecting the stent to the graft. Regarding claims 10, 12-15 and 18, Rhee et al discloses making the compositions readily degradable for drug delivery (Col 15, lines 57-67). Modification in view of Rhee et al, is motivated by mere substitution of functionally equivalent materials and does not destroy the Calcote, Kocur et al or combination by sealing the openings, because the so call seal is permeable to control release. Regarding claims 10-11 and 13-15, Pacetti et al discloses the sample polymers for containing therapeutic agent and diffusing (col 12, lines 35-54) and that the agent may be added as particles (col 9, lines 49-50). Modification in view of Pacetti et al, is motivated by mere substitution of functionally equivalent materials and does not destroy the Calcote, Kocur et al or combination sealing the openings, because the so call seal is permeable to control release. Both Calcote and Kocur et al support inflating a channel with a treatment material and both Rhee et al and Pacetti et al teach treatment material within the art.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Specification

The disclosure is objected to because of the following informalities: [0022], page 8 refers to a co-pending application but has been amended to include the application number of this case.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kocur et al in view of Calcote. Kocur et al discloses a graft (fig. 1A) comprising: a graft body 10 section having a proximal end, a distal end, and defining at least one inflatable porous channel 15; a connector member affixed to the proximal or distal end of the graft body section (abstract, "attached" inherently include one or more connector elements such as the disclosed adhesive or weld/fuse), the connector member comprising one or more connector elements; a stent comprising one more proximal stent connector elements coupled to the one or more connector member connector elements (abstract, "attached"),and an inflation medium including at least one therapeutic agent (abstract) configured to be introduced into the inflatable channel. However, Kocur et al remains silent as to a channel configuration such as at least one inflatable porous cuff disposed at the proximal or distal end of the graft body section and in fluid communication with the at least one channel. Calcote discloses another graft including a

channel configuration such as at least one inflatable porous cuff disposed at the proximal 48 and distal end 46 of the graft body section and in fluid communication with the at least one channel 44 for the purpose of distributing drug to the graft ([0027]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to configure the channels of Kocur et al in the configuration of at least one inflatable porous cuff disposed at the proximal and distal end of the graft body section and in fluid communication with the at least one channel as taught by Calcote in order to distributing drug to the graft. Such a modification amounts to mere substitution of one functionally equivalent drug distribution system for another within the art of grafts.

Claims 1-10, 12-15, 18-19 and 36-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kocur et al in view of Calcote and Rhee et al. Kocur et al discloses a graft (fig. 1A) comprising: a graft body 10 section having a proximal end, a distal end, and defining at least one inflatable porous channel 15; a connector member affixed to the proximal or distal end of the graft body section (abstract, "attached" inherently include one or more connector elements such as the disclosed adhesive or weld/fuse), the connector member comprising one or more connector elements; a stent comprising one more proximal stent connector elements coupled to the one or more connector member connector elements (abstract),and an inflation medium including at least one therapeutic agent (abstract) configured to be introduced into the inflatable channel. However, Kocur et al remains silent as to a channel configuration such as at least one inflatable porous cuff disposed at the proximal or distal end of the graft body section and in fluid communication with the at least one channel. Calcote discloses another graft

including a channel configuration such as at least one inflatable porous cuff disposed at the proximal 48 and distal end 46 of the graft body section and in fluid communication with the at least one channel 44 for the purpose of distributing drug to the graft ([0027]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to configure the channels of Kocur et al in the configuration of at least one inflatable porous cuff disposed at the proximal and distal end of the graft body section and in fluid communication with the at least one channel as taught by Calcote in order to distributing drug to the graft. Such a modification amounts to mere substitution of one functionally equivalent drug distribution system for another within the art of grafts.

Kocur et al also remains silent as to the use of a host polymer for containing the bioactive materials. It is well known in the art of stents to use a host biodegradable polymer to contain bioactive materials for the purpose of sustained release over time. Rhee et al demonstrates the use of host polymer (polyethylene glycol, a curable liquid) for containing bioactive material(s) in conjunction with a graft (col 18, line 21). It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize polyethylene glycol as a bioactive delivery material in the graft of Kocur et al in order to sustained release over time. Such a modification amounts to mere substitution of one functionally equivalent bioactive delivery material for another within the art of grafts.

With respect to claim 4, the porous channel has varying levels of porosity ([0062]).

With respect to claims 5 and 6, the graft body section comprises expanded polytetrafluoroethylene ([0054]).

With respect to claims 7 and 8, Kocur et al discloses a graft as discussed above including

one of the objects of the Kocur et al reference is to tune release quantities and times (the full disclosure), therefore it would be inherent and would be fully capable of releasing agent into the body lumen ranges from about 10 micrograms to about 100 milligrams and transport into the body lumen in a time period ranging from about seven days to about twelve months.

With respect to claim 9, the at least one therapeutic agent comprises one or more agents selected from the group consisting of an endothelialization promoting agent, an angiogenesis promoting agent, an anti-thrombotic agent, an anti-aneurysmal agent, an anti-infection agent, an anti-inflammatory agent, an anti-restenosis agent, a chemotherapeutic agent, and an anti-cancer agent (several are listed [0037]-[0051]).

With respect to claim 13, the graft body section would inherently and would be fully capable of inhibiting transport of a bulk of the host polymer, since it is the same material disclosed by the applicant.

With respect to claim 14, the host polymer is fully capable of being introduced into the inflatable channel before, during, or after graft deployment or implantation, since it is initially a liquid, which is injectable.

With respect to claim 18, polyethylene glycol is a curable liquid which would inherently and would be fully capable of a cure time ranging from about three minutes to about twenty minutes and a post-cure elastic modulus ranging from about 50 psi to about 400 psi, since it is the same material disclosed by the applicant.

With respect to claim 19, the channel comprises one or more features selected from the group consisting of helical spirals, longitudinal channels, and circumferential rings (figs. 1-5).

With respect to claims 37-40, polyethylene glycol diacrylate is a well known type of

polyethylene glycol used for drug delivery and evidenced by it disclosure in the Rhee et al reference (background of the invention)

Claims 1-11, 13-15, 18, 19 and 36-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kocur et al in view of Calcote and Pacetti et al. Kocur et al discloses a graft (fig. 1A) comprising: a graft body 10 section having a proximal end, a distal end, and defining at least one inflatable porous channel 15; a connector member affixed to the proximal or distal end of the graft body section (abstract, "attached" inherently include one or more connector elements such as the disclosed adhesive or weld/fuse), the connector member comprising one or more connector elements; a stent comprising one more proximal stent connector elements coupled to the one or more connector member connector elements (abstract, "attached"),and an inflation medium including at least one therapeutic agent (abstract) configured to be introduced into the inflatable channel. However, Kocur et al remains silent as to a channel configuration such as at least one inflatable porous cuff disposed at the proximal or distal end of the graft body section and in fluid communication with the at least one channel. Calcote discloses another graft including a channel configuration such as at least one inflatable porous cuff disposed at the proximal 48 and distal end 46 of the graft body section and in fluid communication with the at least one channel 44 for the purpose of distributing drug to the graft ([0027]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to configure the channels of Kocur et al in the configuration of at least one inflatable porous cuff disposed at the proximal and distal end of the graft body section and in fluid communication with the at least one channel as taught by Calcote in order to distributing drug

to the graft. Such a modification amounts to mere substitution of one functionally equivalent drug distribution system for another within the art of grafts.

Kocur et al also remains silent as to the use of a curable liquid host polymer for containing the bioactive materials. It is well known in the art of stents to use a curable liquid host polymer to contain bioactive materials for the purpose of sustained release over time. Pacetti et al demonstrates the use of curable liquid host polymer (polyethylene-co-vinyl alcohol, in the summary of the invention and polyethylene glycol diacrylate, col 5, lines 11-30) for containing bioactive material(s) in conjunction with a graft (abstract). It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize polyethylene-co-vinyl alcohol or polyethylene glycol diacrylate as taught by Pacetti as a bioactive delivery material in the graft of Kocur et al in order to sustained release over time. Such a modification amounts to mere substitution of one functionally equivalent bioactive delivery material for another within the art of grafts.

With respect to claim 4, the porous channel has varying levels of porosity ([0062]).

With respect to claims 5 and 6, the graft body section comprises expanded polytetrafluoroethylene ([0054]).

With respect to claims 7 and 8, Kocur et al discloses a graft as discussed above including one of the objects of the Kocur et al reference is to tune release quantities and times (the full disclosure), therefore it would be inherent and would be fully capable of releasing agent into the body lumen ranges from about 10 micrograms to about 100 milligrams and transport into the body lumen in a time period ranging from about seven days to about twelve months.

With respect to claim 9, the at least one therapeutic agent comprises one or more agents

selected from the group consisting of an endothelialization promoting agent, an angiogenesis promoting agent, an anti-thrombotic agent, an anti-aneurysmal agent, an anti-infection agent, an anti-inflammatory agent, an anti-restenosis agent, a chemotherapeutic agent, and an anti-cancer agent (several are listed [0037]-[0051]).

With respect to claim 13, the graft body section would inherently and would be fully capable of inhibiting transport of a bulk of the host polymer, since it is the same material disclosed by the applicant.

With respect to claim 14, the host polymer is fully capable of being introduced into the inflatable channel before, during, or after graft deployment or implantation.

With respect to claims 18, polyethylene-co-vinyl alcohol and polyethylene glycol diacrylate are a curable liquids which would inherently and would be fully capable of a cure time ranging from about three minutes to about twenty minutes and a post-cure elastic modulus ranging from about 50 psi to about 400 psi, since it is the same material disclosed by the applicant.

With respect to claim 19, the channel comprises one or more features selected from the group consisting of helical spirals, longitudinal channels, and circumferential rings (figs. 1-5).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Wu et al. (US 6,656,506) and Gould et al. (US 4,439,585).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J. Sweet whose telephone number is 571-272-4761. The examiner can normally be reached on 5:45am - 4:15pm, Tu-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thomas J Sweet
Examiner AU 3738